Appl. No. 09/431,607 Amdt. dated March 16, 2004 Reply to Office Action of December 16, 2003

REMARKS/ARGUMENTS

Upon entry of this amendment, claims 24-29 are pending in this application and are presented for examination. Claim 24 has been amended. No new matter has been introduced with the foregoing amendment. Reconsideration is respectfully requested.

I. DRAWINGS

In the Office Action, the Examiner indicated that Figures 14 and 15 were missing in the application as filed. However, the postcard acknowledging receipt of the instant application shows that 15 sheets of drawings, *i.e.*, corresponding to Figures 1-15, were originally filed. A copy of the postcard is attached hereto as Exhibit 1. It is noted that Figures 15, 14, and 13 may have been placed, in that order, after Figure 12 in the application as originally filed in the U.S.P.T.O. However, for the convenience of the Examiner, copies of Figures 14 and 15 as originally filed are attached hereto. As such, no new matter has been introduced in the drawings.

II. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 24-29 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the Applicants, at the time the application was filed, had possession of the claimed invention. To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

The Examiner alleges that there is a lack of data or suggestion in the specification indicating that 5,5-Dithiobis(2-Nitrobenzoic Acid) ("DTNB") should be excluded from disulfides having the formula R-S-S-R. In response, Applicants assert that there is sufficient data in the specification as filed showing that DTNB does not disrupt viral nucleocapsid ("NC") protein structure in intact retroviruses and does not inactivate mature, infectious retroviruses.

As set forth in Example 4 of the instant application, disulfide reagents disrupt NC structure by causing inter-NC cysteine disulfide bonds, *i.e.*, cross-links, in *intact* retroviruses (*see*, page 29, lines 18-22). Although Table 2 in Example 4 shows that DTNB cross-links NC proteins at a "fast" rate, such experiments were performed on *purified*, *recombinant* HIV p7NC

protein, and not on *intact* retroviruses (*see*, Example 4, from page 28, line 29 to page 33, line 10). However, Figure 15A of the instant application clearly shows that DTNB does not cause cross-linking of NC proteins in *intact* retroviruses, as the NC protein structure of intact HIV-1 retroviruses treated with DTNB (lane 5) was nearly indistinguishable from the NC protein structure of intact HIV-1 retroviruses alone (lane 1). In stark contrast, the NC protein structure was disrupted by disulfide reagents such as Aldrithiol-2 ("D1b," lane 8) and 2,2-Dithiobis(Pyridine N-Oxide) ("E1d," lane 9). As such, Applicants submit that the instant specification provides sufficient data showing that DTNB does not disrupt NC protein structure in *intact* retroviruses.

In addition, Figure 15B of the instant application clearly shows that DTNB does not inactivate mature, infectious retroviruses. The graph in Figure 15B presents the concentration of a compound ("Drug") required to inactivate half of a standardized number of mature, infectious retroviruses in a tissue culture infectivity assay ("TCID-50"). As shown in Figure 15B, increasing concentrations of disulfide reagents such as Aldrithiol-2 ("D1b") and Formamidine Disulfide ("C4b") are effective at inactivating mature, infectious retroviruses. In stark contrast, DTNB had no effect on mature, infectious retroviral inactivation, even at the highest concentration tested. As such, Applicants submit that the instant specification provides sufficient data showing that DTNB does not inactivate mature, infectious retroviruses.

In view of the foregoing, Applicants believe that the application as originally filed provides sufficient basis for excluding DTNB from the list of compounds that can be used to inactivate a retrovirus. Therefore, Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 112, first paragraph rejection.

III. REJECTION UNDER 35 U.S.C. § 102(b)/103(a)

Claims 24, 28, and 29 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by, or, in the alternative, under 35 U.S.C. § 103(a) as allegedly being obvious over Levine *et al.*, WO 92/15329. To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

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The Examiner alleges that the disruption of CCHC zinc fingers would be an inherent property of the copper ions of Levine *et al*. In order to expedite prosecution of the present case, Applicants have amended claim 24 to delete "cupric ions and complexes containing Cu⁺²." In view of the amendment to claim 24, Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 102(b)/103(a) rejection.

IV. DOUBLE PATENTING REJECTION

Claims 24-29 were rejected under the judicially created doctrine of obviousness-type double patenting for allegedly not being patentably distinct over claims 1, 6-9, and 25-28 of U.S. Patent No. 6,001,555. In the Office Action, the Examiner has indicated that the double patenting rejection can be overcome by the filing of a Terminal Disclaimer (*see*, page 5 of the Office Action).

Applicants respectfully request that this obviousness-double patenting rejection be held in abeyance until Applicants receive from the Examiner an indication regarding allowable subject matter. At that time, Applicants will file a Terminal Disclaimer as suggested by the Examiner.

V. CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

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If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,

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Attachments EGW:jch

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PATENT APPLICATION FILING ACK OWLEDGMENT

Mailing Date:	11/1/99			
File No.: 15280-	-169300US	Attorney:	GPE:mys	
Inventor(s): Louis E. Henderson, Larry O. Arthur, William G. Rice, et al.				
Title: ME	METHOD FOR IDENTIFYING AND USING COMPOUNDS THAT			
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EXHIBIT1
